

REMARKS**I. Status of the Claims**

Claims 1, 2 and 4 are cancelled. Claims 3, 5 and 6 are pending. Because the amendment of June 23, 2004 was not entered, the amendments herein are based on the January 6, 2004 submission.

II. Undue Experimentation is Not Required to Determine Bacteria that are Within Claim Scope.

The invention relates methods and compositions to detect a host (swine) genotype that is resistant to “colonization” of intestines by “toxigenic” bacteria that can “adhere to the swine intestinal walls” because the bacterial have fimbriae. Claim 3 is amended to relate a group of *E. coli*, that is, “toxigenic *E. coli*” with fimbriae that make them capable of “adhering” to the swine small intestine, “colonizing”, and producing toxins that cause “intestinal disorders”. Support for these terms are found in the specification at least in the following locations.

<u>page</u>	<u>line</u>	
1	15	“toxigenic”
1	21-22	disease causing toxins produced by colonizing <i>E. coli</i>
1	27-28	“The <i>E. coli</i> are distinguished by their pili types, of adhesive fimbriae...”
2	8-13	mechanism of resistance
9-10	Example 2	test for adhering bacteria
18	Par 7	colonization test

E. coli F18 is one bacterial strain that fits criteria of the invention, but claims should not be limited to this strain because, e.g. if the strain name changed, or a new strain is found with the same characteristics, those using the strain might escape infringement despite their method falling within the scope of the present invention. Also, case law indicates claims should not be limited to an embodiment, even if only one embodiment is in the specification. The specifications need not list every embodiment of the invention that the inventor wishes to protect through the claims of the patent. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898 (Fed. Cir. 2004), *Mars Inc. v. H.J. Heinz Company L.P.*, 377 F.3d 1369 (Fed. Cir. 2004).

As shown in Example 2, no undue experimentation is needed to determine whether bacteria e.g. *E. coli* is capable of adhering to swine intestines. An assay is available, here used to determine resistant swine, but the assay can be used to visualize adhering bacteria.

A colonization test is related in paragraph 7 of the Materials and Methods.

The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998)(citing *PPG Indus., Inc. v. Gardian Indus. Corp.*, 75 F.3d 1158, 1564, 37 USPQ2d (BNA) 1618, 1623 (Fed. Cir. 1996)).

The invention also is directed to use of DNA closely linked to the FUT1 polymorphism. The specification discloses a specific polymorphism M307 in FUT1 that is associated with resistance to *E. coli* colonization and discloses methods to identify polymorphisms by direct sequencing and correlative linkage analysis. As the examiner states,

The specification supports generally that the allele is associated with resistance to F18, however there is no nexus that the phenotype is a direct consequence of the allele and not some other gene at that loci or tightly associated with the allele.

Advisory Action

Given M307 as an “anchor marker” in determining disease resistance to *E. coli* infection in swine and the disclosure in the specification, it is within the level of skill in the art to identify


closely associated polymorphisms that are in allelic association with M307 and screen for *E. coli* that are capable of causing intestinal disease in swine.

Claims 3 and 5 are also amended to relate uses of DNA in "allelic association" with the FUT1 polymorphism (Example 8). Support for "allelic association" can be found at least on page 7, lines 17-20, and page 12, Example 8 of the specification. This scope is to prevent others escaping literal infringement by using FUT1 as an anchor marker disclosed in the present invention, to locate a section of closely linked DNA to accomplish the same goal as the claimed invention.

Applicants believe that the amended claims in light of the foregoing arguments are in allowable form and request that the 112 rejections be withdrawn.

Please contact applicants' representative if there are other issues. No additional fees are believed due at this time, however, please charge any deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (21419-91512).

Respectfully submitted,



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